HKU School of Professional and Continuing Education

Research Ethics Committee

<u>Operational Guidelines and Procedures</u>

This is an abridged version of the "Operational Guidelines and Procedures" of the Human Research Ethics Committee (HREC) of the University, with amendments made by the HKU SPACE Research Ethics Committee (REC). The full document is available on the HKU Research Services website at <u>www.rss.hku.hk/HREC/guidelines.pdf</u>. All members of the University including HKU SPACE are under an obligation to comply with the highest standards of professional conduct. All research conducted by staff and students involving human participants subjects must be referred to the Research Ethics Committee (REC) for consideration.

The following guidance notes on how to obtain ethical approval from the REC are intended to provide the necessary information for Principal Investigators (PIs) to complete the application form for ethical approval. The Application Form for Ethical Approval can be downloaded from the HKU SPACE Staff Intranet, Learner Portal and Learners' Information on the School's website.

1. <u>Research Requiring Ethical Review</u>

   Research requiring Ethical Review include all research projects / dissertations / theses involving human participants by HKU SPACE staff, taught postgraduate and undergraduate students who are Principal Investigators (PIs) of the project. Such research will have a potential for invading human privacy, such as written questionnaires, telephone surveys, interviews, observations, video-taping and audio-taping, case study of focus groups, secondary use of data (not for a directly related purpose when the data was collected), deception, testing (non-invasive, not involving drugs), and non-medical treatment or intervention.

   For ethics research approval granted to staff by other academic institutions, the REC will normally just receive and note the approval that they already obtained from the institutions unless the Committee has concern on the related ethics research proposed by the staff.

   When HKU SPACE staff or students engage (other than as research participants) in research projects led by other universities / organizations that involve human participants in the research investigations, if any part of the data collection is organized through or in the name of HKU SPACE, and / or if the project involves human research participants in HKU SPACE, the responsible person from HKU SPACE (including staff and students) should seek ethics approval from HKU SPACE. For research projects without any HKU SPACE staff and students participating as PIs or Co-Is that involve human research participants in HKU SPACE, the PI of the project should seek ethics approval from HKU SPACE to ensure that the human research participants in HKU SPACE are well protected.

   Exemption from ethics approval will only apply to anonymous surveys for improving teaching and learning (not for research) which are exclusively for the University's internal usage.

2. Ethical Guidelines for Research involving Human Participants

Researchers should note the principles concerning the areas in the following list when conducting non-invasive research as outlined in "Operational Guidelines and Procedures" of the Human Research Ethics Committee for Non-Clinical Faculties (HREC), Clause V. For details, please see the following link: www.rss.hku.hk/HREC/guidelines.pdf.

– Sources of Data
– Risk Assessment
– Informed Consent
– Recorded Consent Other Than Written Consent
– Waiver of the Requirement of Recorded Informed Consent
– Pre-existing Data
– Pilot Studies
– Parental Consent and Student Assent
– For School-based Research
– For Adolescent Research Outside School
– For Studies of HKU SPACE
– Privacy and Confidentiality of Data
– Security
– For Studies Involving External Parties
– Benefits: Prospective participants should not be adversely induced by financial reward or be pressured to participate in research. All reimbursement of expenses, such as travelling expenses, should be commensurate with standard practice and be reasonable.

3. Types of Review

The REC conducts three types of review i.e. expedited review, double review and full review. In general, for a research protocol which involves only minimal risks[1] to human beings, an expedited review may be conducted to shorten the review process, subject to the Chairman's discretion. If not, the application will go through double review or full review by the Committee.

I. *Expedited Review (submitted to the REC for vetting, then normally approved within two to three weeks)*

Projects involving no greater than minimal risk may be considered by the Committee under "expedited review". That is to say, the nature of the research meets one of the following definitions:

---

[1] As defined by the Institutional Review Board of the University of Hong Kong / Hospital Authority of Hong Kong West Cluster ("IRB") in its Standard Operation Procedures (2005), "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test.

(a) Research, involving the collection or study of existing documents or records containing personal data[2], if these sources are publicly available[3] or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to the participants. The source of data, documents, records, must be indicated in the application form for the Committee's consideration.

(b) Research involving anonymous data[4] collected using educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behaviour. Expedited review cannot be granted to:

(i) information obtained that is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and

(ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

II. *Double Review (submitted to the REC for vetting, then normally approved within three weeks)*

Research that does not fulfill the description of minimal risks will normally require double review by at least two members of the Committee.

III. *Full Review (submitted to the REC for vetting, approved within one month)*

Research involving any of the following items will require full review:

(a) Sensitive topics which could induce stress to research participants, such as illegal conduct, drug or alcohol use and sexual conduct;

(b) Deception, (participants are given misleading information during the research process). The PI must justify in detail why the method of deception is necessary and why there will not be any adverse psychological and / or emotional harm. Participants will need to be debriefed at the end of the study. (A Sample of English and Chinese post-debriefing consent forms to participants are in www.rss.hku.hk/integrity/ethics-compliance/hrec-forms);

(c) Action / participatory research which involves greater than minimal risk;

(d) Treatment research;

---

[2] As defined by the Personal Data (Privacy) Ordinance, "personal data" means any data (a) relating directly or indirectly to a living individual; (b) from which it is practicable for the identity of the individual to be directly or indirectly ascertained; and (c) in a form in which access to or processing of the data is practicable.

[3] "Publicly available" means that the general public can obtain the data. Sources are not considered "publicly available" if access to the data is limited to researchers.

[4] Anonymous data: Data without personal identifier (e.g. name, ID card, DNA profile). Data is anonymous when there is no possible way to identify the participants from the data collected. Data is not anonymous if procedures, such as accessing a computer database, will identify the participant. For most specific cases, the omission of names and other personal identifiers as HKID / Passport numbers, is sufficient to qualify data as anonymous.

(e) Inclusion of participants who may be unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals (unless the criteria for expedited review are met);

(f) Study can induce psychological stress / pain / discomfort; and

(g) Video-taping and audio-taping, that pose privacy risk.

4. <u>Procedures to be Followed when Applying for Ethical Approval</u>

The supervisor / tutor and the Programme Leader (for part-time programme) / College Head / Programme Co-ordinator (for full-time programme) in-charge are responsible for determining if each student's project needs ethical clearance and for overseeing the completion of the necessary application for ethical approval. Students as well as Staff who initiate ethics research should submit their applications to the REC for vetting via the Secretary of the Committee. Cases that require a full review or have some issues of concern would be referred to the HREC.

I. *Obtaining Prior Ethics Approval*

It is the responsibility of the PI to make sure that ethics approval has been obtained prior to any data collection / analysis taking place.

II. *Deadlines for Submission*

There is no deadline for applications for ethical clearance. The processing time from submission of application to notification of approval will normally take not more than 3 weeks, provided that the submitted application form is properly completed with all required documents attached.

III. *Documents to be Completed and Submitted*

The application form, the standard templates of informed consent form can be downloaded from the website (https://hkuspace.hku.hk/teaching-and-learning/learners-support/learners-information/research-ethics-committee). Please submit the online application, a full research proposal, and questionnaire and / or interview script and informed consent form (if any) to the Secretary of the Committee c/o Room 313, 3/F, Admiralty Learning Centre, HKU SPACE.

5. <u>The Outcome of the Review</u>

The Committee will normally notify the applicant by email of the result of application within 3 weeks' time from receipt of his / her duly completed application with all required documents. Research cannot begin until the protocol has been approved by the Committee.

I. *Approved*:

A letter / email of approval will be issued to the Applicant (student / staff member) and copied to the Supervisor and / or Programme Leader.

II. *Conditionally Approved:*

The approval letter / email is issued with conditions that apply to the approval that need to be satisfactorily addressed. Normally such conditions should be addressed with the applicant in advance.

III. *Approval is Not Given and Resubmission:*

The Committee will specify its comments / recommendations that need to be addressed in a resubmission on the notification to the PIs / Supervisors / Students of protocols which are not approved.

IV. *Reconsideration of Decision:*

The Committee will further consider the resubmitted proposals according to the Committee's recommendations.

6. <u>Legal, Ethical and Safety Compliance</u>

It is the responsibility of the PI to make sure that the research proposal submitted to the Human Research Ethics Application System is carefully reviewed for its compliance with applicable laws (including those of Hong Kong and / or those of other relevant jurisdictions), ethical standards, and health and safety guidelines. Any illegal, unethical or unsafe action / activity must be avoided throughout the research process.

Researchers should, in particular, note the following principles when conducting research that may involve research participants who are / were engaged in activities in breach of (or potentially in breach of) the applicable laws (including those of Hong Kong and / or those of other relevant jurisdictions):

I. serious and due consideration must be given to whether or not such involvement is well justified taking into account such factors as academic merit, alternative research methods and sources, potential risks, mitigation measures and interests of stakeholders;

II. there must not be any act, conduct or activity that may bring the University into disrepute; there must not be aiding, abetting, counselling or incitement in respect of any offence or potential offence;

III. legal duties to report or disclose as required under the applicable laws must be discharged (e.g. legal provisions in respect of offences of drug trafficking, money laundering, terrorism, national security, etc.);

IV. there must not be obstruction to criminal or other investigations by the competent authorities or the commission of acts tending to pervert the course of justice;

V. requests for the disclosure of information / documents (including confidential information / documents) as required under the compulsion of applicable laws must be complied with; and

VI. in the informed consent form, in addition to being provided with general information, prospective research participants must be informed of the risks and circumstances in which confidentiality may not be maintained (e.g., compulsion by relevant legal authorities to hand over research materials or answer questions) and what additional safeguards the PI will therefore undertake to protect the integrity of the research and the identity of the research participants, subject to compliance with the applicable laws.

In the event that an ethics application involves research participant(s) under investigation by a competent authority or participant(s) subject to legal proceedings in court or otherwise

(criminal, civil or disciplinary), the University will normally suspend the processing of the ethics application until the completion of the relevant investigation or legal proceedings.

7. Progress Monitoring

The PIs of all active research projects are required to report to the REC any amendments and new information on the project. Any deviation from the study protocol or compliance incident that has occurred during a study and may adversely affect the rights, safety or well-being of any participant or breaches of confidentiality should be reported to the REC within 15 calendar days from the first awareness of the deviation / incident by the PI.

8. How to Maintain Ethical Standard in Research

I. *Right to Appeal*

(a) The REC can refer special cases requiring advice to the HREC for informal advice;

(b) All research participants have the right to appeal and to refer any concerns or questions directly to the HREC; and

(c) A statement informing participants of their right as research participants to contact REC directly if they have any concerns or questions should also be provided on all recruitment materials, consent forms, information sheets, and debriefing notes for dispatch to all research participants. All recruitment materials and consent forms must include a readily reachable contact of the PI or relevant personnel of the study for participants' enquiries about details of the study (normally a telephone number for studies conducted in Hong Kong, and an email address for overseas studies), the REC's email address (rec@hkuspace.hku.hk) for enquiries about participants' rights. For surveys conducted by telephone and / or self-administered questionnaire, REC's email address (rec@hkuspace.hku.hk) and also the PI concerned must be provided before data collection starts (but can be after selection of a respondent).

II. *Annual Reporting*

An annual statistical report on the number of approved applications / re-submissions and any acute incidents which have occurred, to the HREC and the HKU SPACE School Academic and Management (SAM) Board by the end of each academic year.

9. Contact Information

For enquiries, please contact the Secretary of the REC c/o Room 313, 3/F, Admiralty Learning Centre, HKU SPACE (email: rec@hkuspace.hku.hk).

January 2024